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(54) **BENT CO-AXIAL CATHETER**

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A61M 3/00 (2006.01)

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See application file for complete search history.

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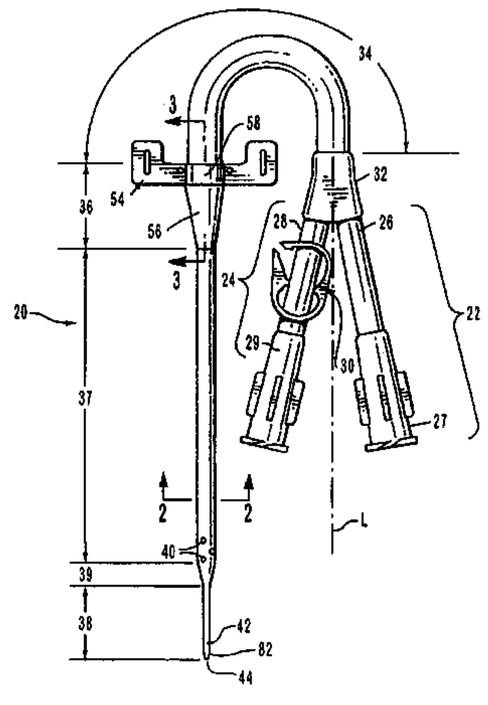
(57) **ABSTRACT**

The invention provides a co-axial dual lumen catheter having a main section, a tip section, and a U-shaped proximal portion extending from the main section, and ending at a junction where intake and outlet tubes are connected to the proximal portion. An inner tube extends from the junction to the tip of the catheter to define a return lumen, and combines with outer tubes in the main section and the proximal portion to define an intake lumen. The inner tube is thin walled relative to the wall thickness of a first outer tube used in the main section, and a second outer tube used in the proximal portion has a greater cross-sectional area than the first outer tube. A proximal end structure is also described in which the intake and outlet tubes extend generally parallel with the main body and to one side of the main body.

43 Claims, 4 Drawing Sheets



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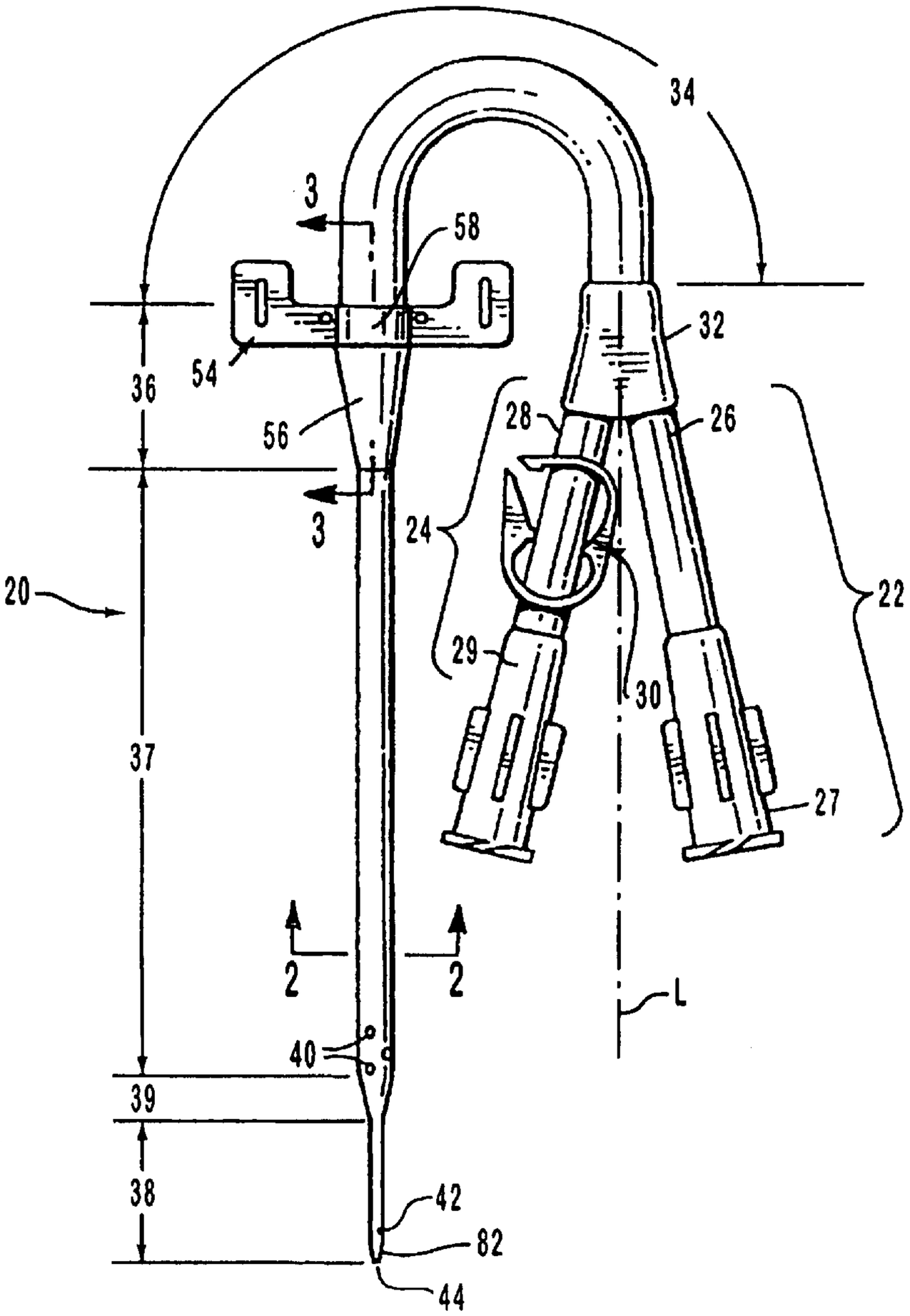

FIG. 1
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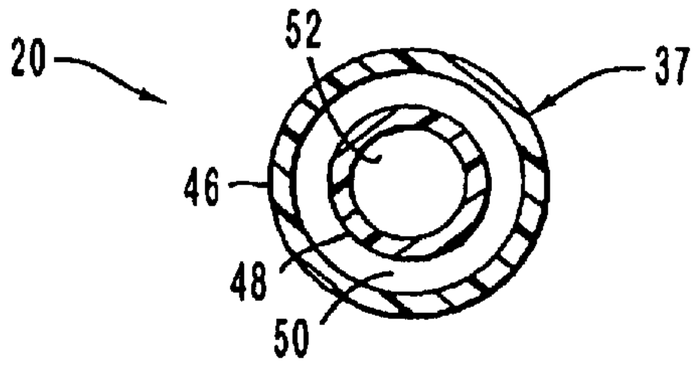

FIG. 2
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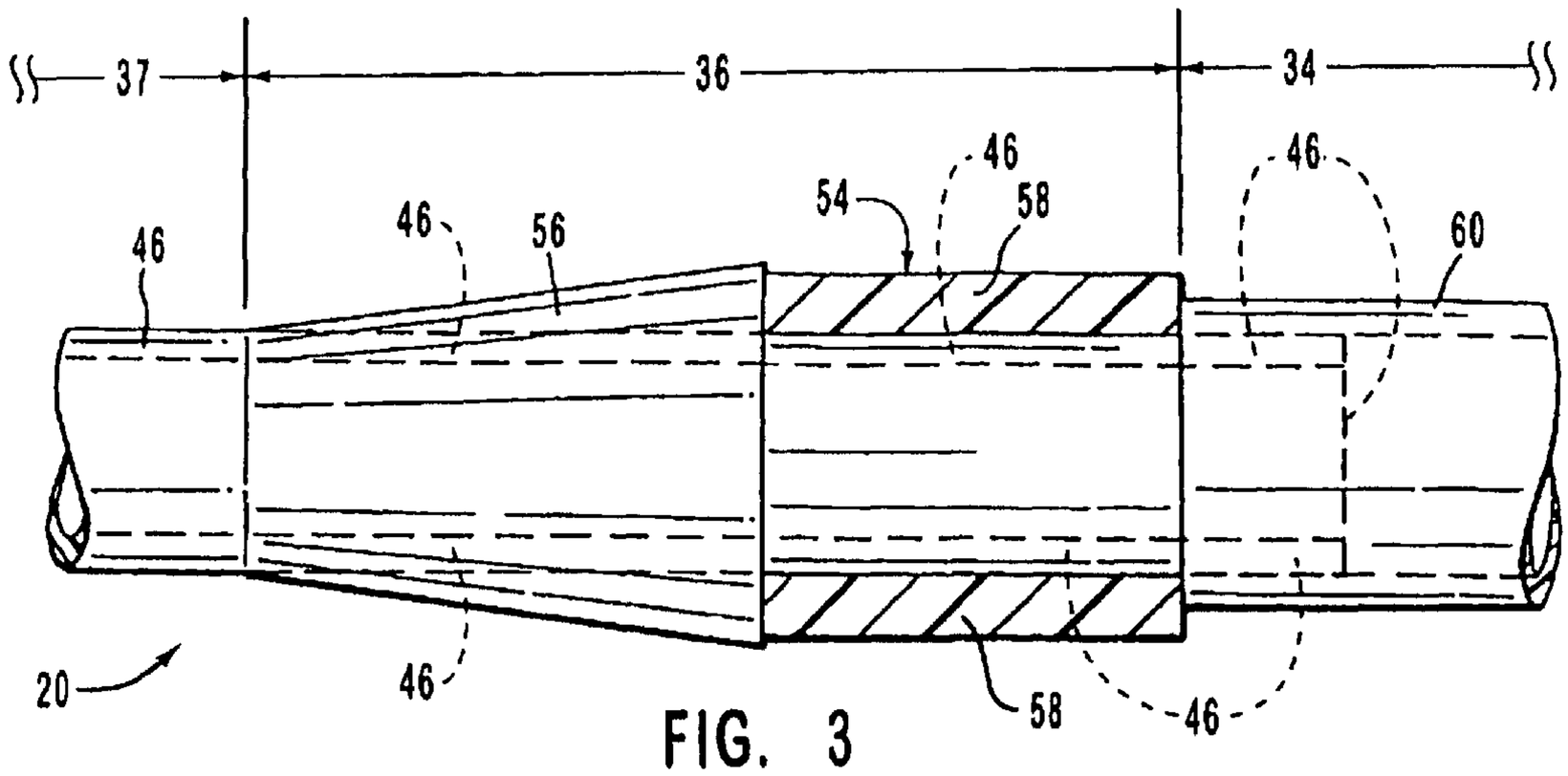

FIG. 3
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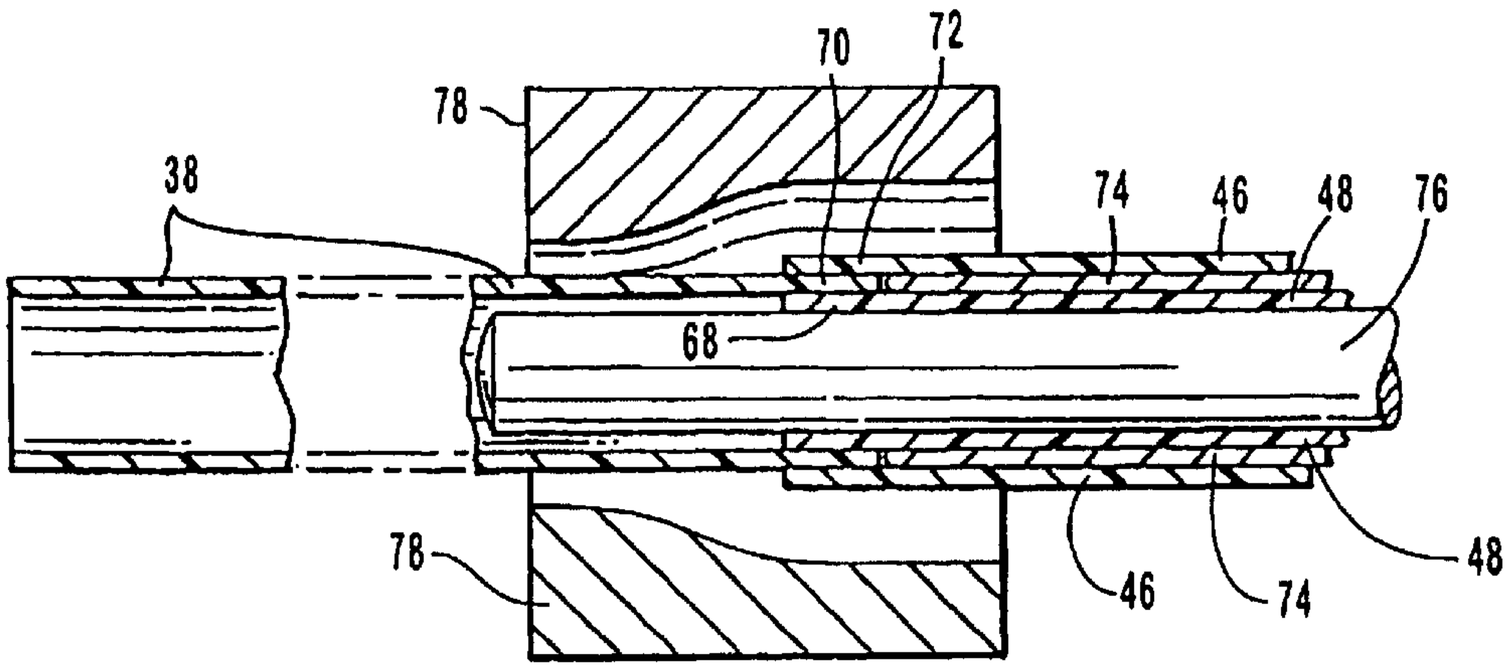

FIG. 4
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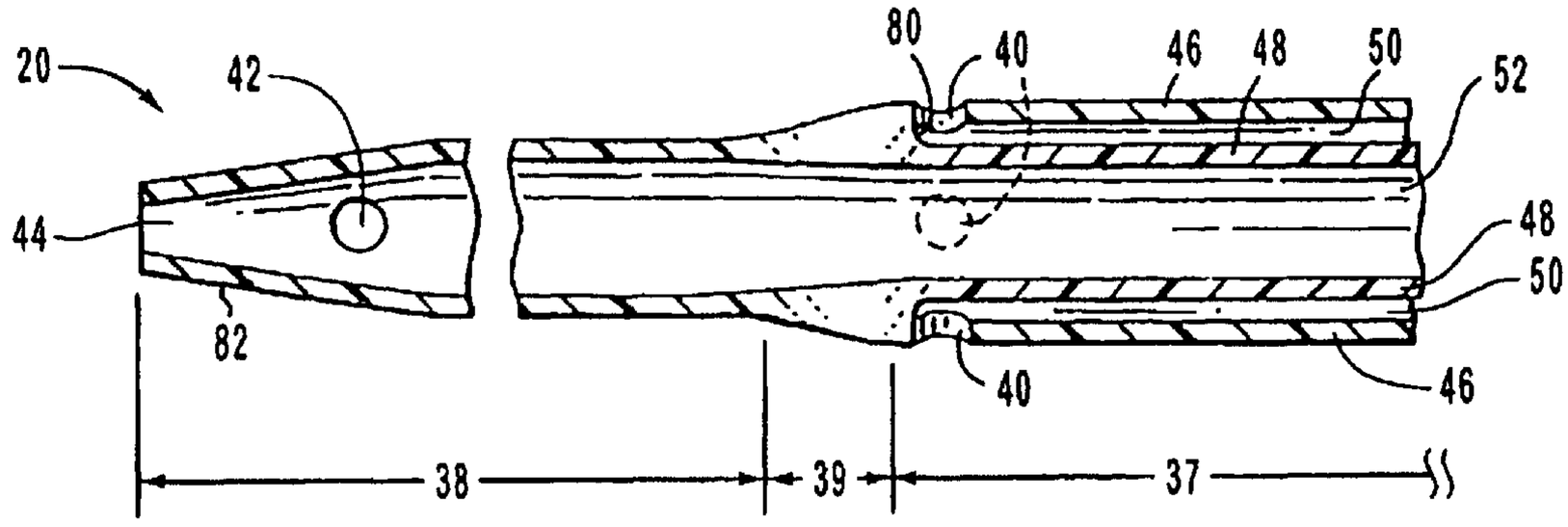

FIG. 5
(AMENDED)

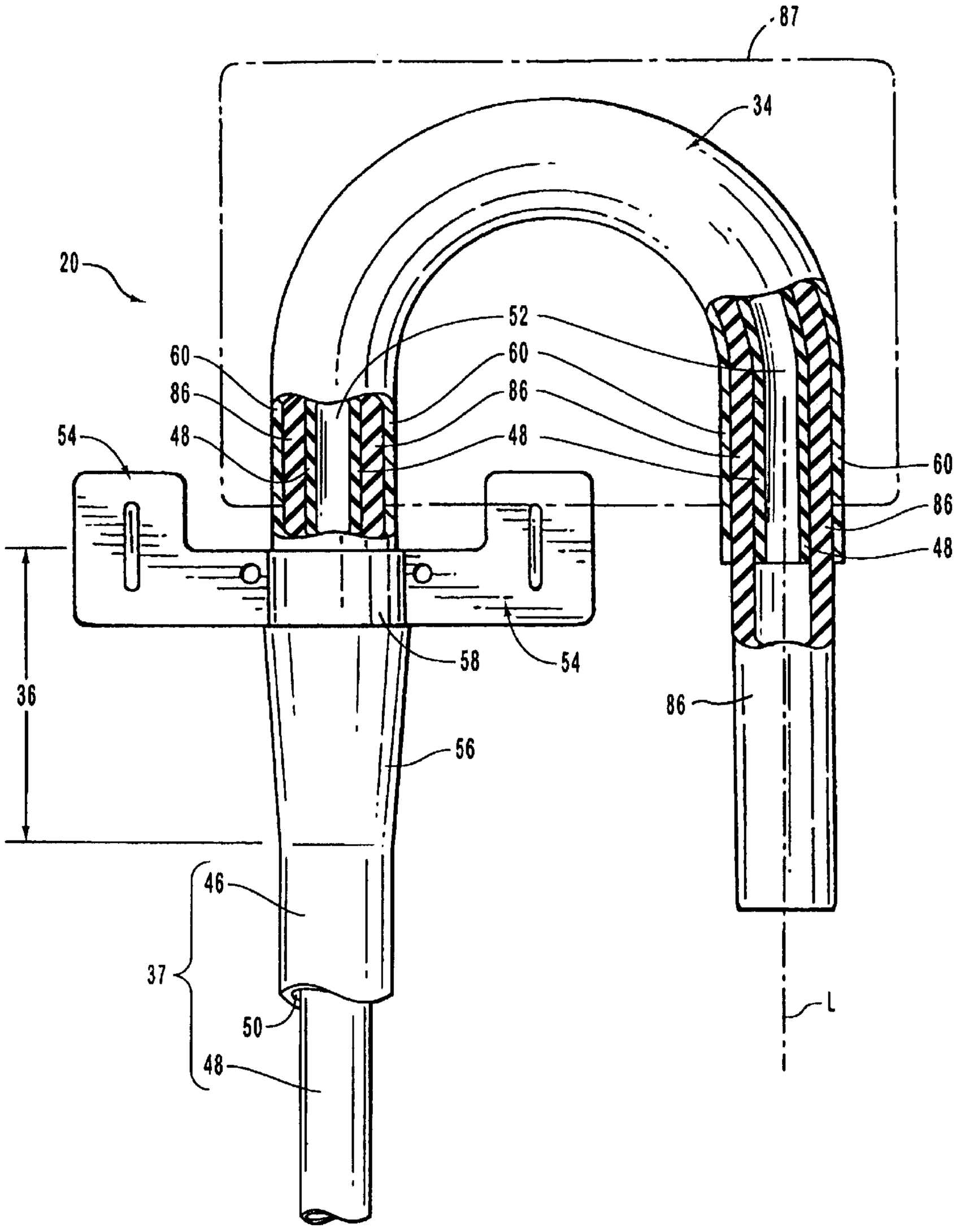

FIG. 6
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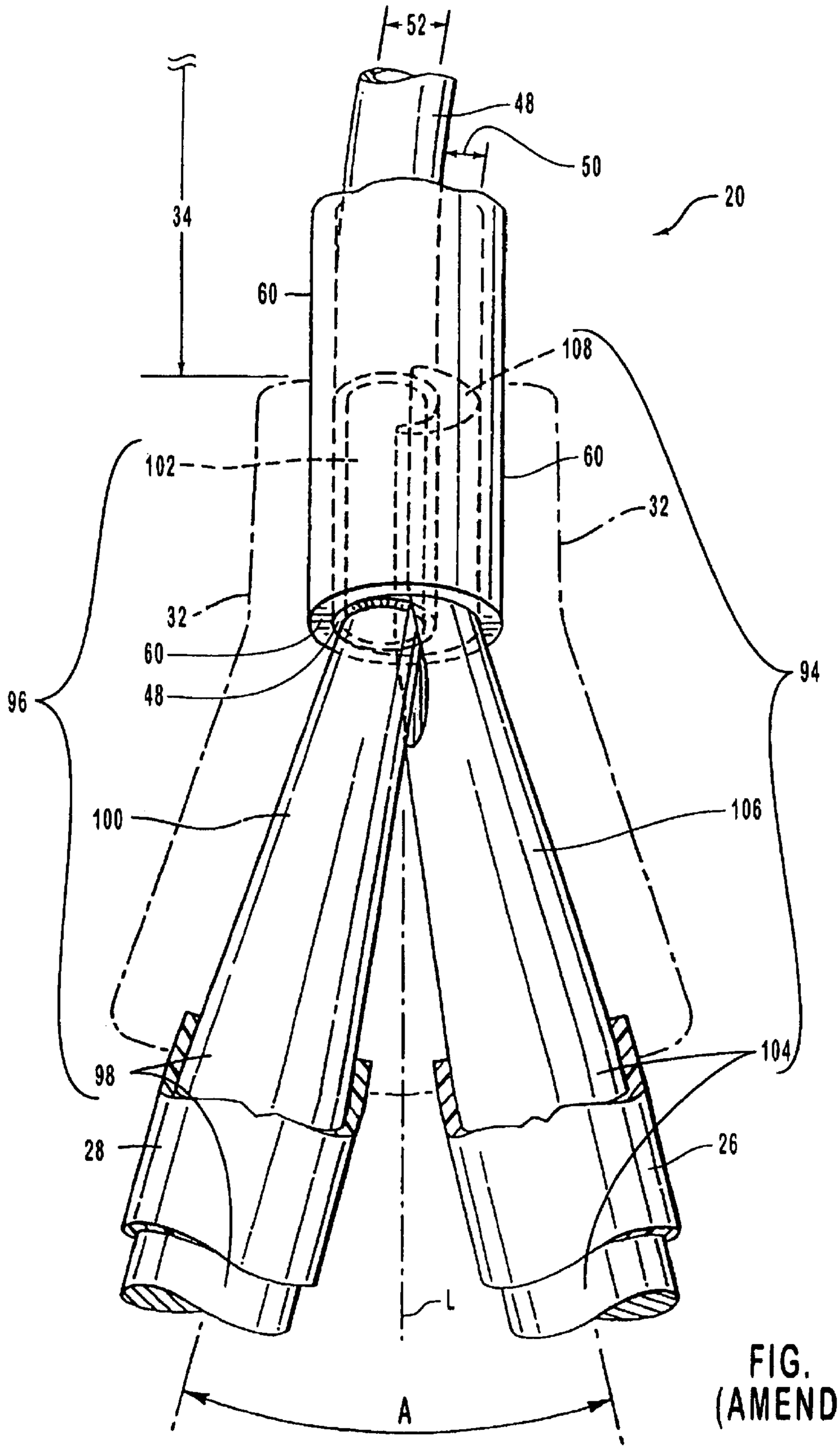

FIG. 7
(AMENDED)

BENT CO-AXIAL CATHETER

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

This invention relates to co-axial dual lumen catheters for use in haemodialysis treatments and more particularly to such a catheter for placement in a jugular vein.

Haemodialysis treatments have been developed since the early 1960s using a variety of combinations and arrangements of catheters. The earliest treatments were conducted using two needles in the same vein and this subsequently led to pioneer work done by Dr. Shaldon in England who used two flexible catheters which could be left in place for limited periods. It was recognized by some practioners that it would be preferable to use a single incision rather than to use two and this led to the development of techniques involving dual flow catheters. There are two basic types. The first to be attempted was a co-axial catheter with the intake lumen surrounding the return lumen. While this had advantages, there were some difficulties of manufacture. The other approach is to use side-by-side lumens either in individual tubes connected to one another or in a single tube divided by an interior septum so that the lumens are D-shaped. Although such structures have become popular with many surgeons, they also had disadvantages. The most notable disadvantage is that because the lumens are side-by-side, the intake openings must be in one side of the catheter. As a consequence of this, there is a tendency for the suction at the opening to draw the catheter towards the wall of a blood vessel with the result that the flow could stop. Medical staff then have to move the catheter by rotating it until blood again flows.

The side-by, side structures have advantages in manufacture due to the fact that the two lumens can be created simultaneously in an extrusion. This has led to great activity in developing devices having side-by-side D-shaped lumens at the expense of co-axial structures. Nevertheless, due to the inherent disadvantages of the side-by-side structures, there has been renewed interest in developing suitable co-axial devices. This is primarily because the intake lumen can have openings in any part of the wall of the catheter.

Dialysis catheters are commonly inserted in either the subclavian or jugular veins. It has been found that the subclavian vein is more desirable from the standpoint of patient acceptance due primarily to the fact that the proximal (i.e. external) portions of the catheter can be readily taped to the patient without interfering significantly with the patient's movements. However, it has been found that jugular placement has resulted in less vein stenosis, and consequently jugular placement is finding more favour among surgeons although the proximal portions of the catheter can be an irritant for the patient because the portions tend to project upwardly near the ear of the patient.

It is therefore an object of the present invention to provide a co-axial catheter particularly for placement in a jugular vein and which has a minimal upwardly projecting proximal portion.

[It is also an object of the invention to provide such a catheter which will also permit periodic rotation of the catheter in place to ensure continued patency.**]**

Accordingly, in one of its aspects, the invention provides a dual lumen catheter having a main body, a tip section at a distal end of the main body, an attachment positioned on the main body for fixing the catheter relative to the patient, a proximal U-shaped portion extending from the attachment, a junction at a proximal end of the U-shaped portion, and a pair of tubes attached to the junction and forming continuations of the respective lumens for coupling the catheter to dialysis equipment.

This and other aspects of the invention will be better understood with reference to the drawings and the following description, in which:

FIG. **1** is a side view of a catheter **[**a**]** *configured* according to **[**a preferred embodiment**]** *teachings* of the *present* invention;

FIG. **2** is a sectional view on line **2**—**2** of FIG. **1** and drawn to a larger scale;

FIG. **3** is a sectional view on line **3**—**3** of FIG. **1** and drawn to the same scale as FIG. **2**;

FIGS. **4** and **5** are diagrammatic views illustrating steps in the procedure of manufacturing the distal end (tip end) of the catheter;

FIG. **6** is a sectional view to a larger scale than that used for FIG. **1** and illustrating a step in the manufacture of a U-shaped proximal portion of the catheter; and

FIG. **7** is a partially sectioned view to a scale larger than that used for FIG. **1** and showing a junction at the proximal end of the catheter and demonstrating both the structure and the method of making the junction.

Reference is made firstly to FIG. **1** which illustrates a co-axial catheter **[**designated generally by the numeral**] 20 [**and**]** *that encloses a pair of distinct, longitudinally extending, fluid flow lumens. Catheter 20 is* useful for withdrawing blood through a**[**n intake**]** *withdrawal structure* **22** and returning treated blood through a**[**n outlet**]** *return structure* **24**. **[**The intake and outlet**]** *Withdrawal structure 22 includes a flexible first tube 26 that communicates with one of the lumens in catheter 20 and that terminates in a first luer connector 27. Return structure 24* includes **[**prospective**]** *a* flexible *second* tube**[**s **26**,**]** **28 [**which**]** *that communicates with the other of the lumens in catheter 20 and that terminates in a second luer connector 29. Each of first tube 26 and second tube 28* can be clamped using conventional devices, such as device **30** shown on *second* tube **28 [**and which terminate at respective luer connectors **27**, **29]**.

[The**]** *First tube 26 and second* tube**[**s**]** *28* meet at a junction **32** at the proximal end of a U-shaped proximal portion **34 [**which**]** *of catheter 20. Proximal portion 34* terminates at **[**its**]** *the* distal end *thereof* in a proximal transition portion **36 [**leading to**]** *of catheter that is 20 located at the proximal end of* a main section **37 [**and hence to**]** *of catheter 20. Main section 37 terminates at the distal end thereof at* a tip section **38 [**which meets the main body at**]** *of catheter 20 and* a distal transition portion **39** *of catheter 20 that is located between tip section 38 and main section 37*. Blood is withdrawn through *withdrawal* side openings **40 [**and**]** *at the distal end of main section 37. Blood* returns through **[**further**]** *return* side openings **42** and end opening **44** *at the distal end of tip section 38*.

As a result of this arrangement **[**the**]** *first and second access* tubes **26**, **28** extend generally in parallel with **[**the**]** main section **37** *of catheter 20* and lie **[**to one**]** *together on the same* side of **[**the**]** *main* section **37**.

As seen in FIG. **2**, **[**the**]** main section **37** includes an outer tube **46 [**containing**]** *enclosing* an inner tube **48**. **[**which**]** *Inner tube 48* also extends through an outer tube **60** in **[**the**]** proximal portion **34 [**as will be explained**]**. **[**The inner**]** *Inner* tube **48** is therefore continuous, having a first part inside

outer tube **46** in [the] main section **37** and [the] *a* second part inside [the] outer tube **60** [forming part of the] *in* proximal portion **34**. [The inner] *Inner* tube **48** is free, but for attachment[s] at [its] *the* ends [as will be explained] *thereof*.

[The] *Inner tube 48 thus freely and loosely extends through outer tube 46 and outer tube 60. Withdrawal* openings **40**, shown in FIG. **1**, supply blood to an intake lumen **50** formed *in part* between [the] *outer* tube[s] **46**[,] *and inner tube* **48** [and, in the] *in main section 37 of catheter 20. In* proximal portion *34 of catheter 20, the balance of intake lumen 50 is formed* between *outer* tube[s] **60** and *inner tube* **48**. Blood returns by a return lumen **52** defined by [the] inner tube **48**.

The junction **32** at the proximal end of the U-shaped proximal portion **34** connects [tubes **48**, **60** to the] *first tube 26 and second* tube[s **26**,] **28** [(as will be explained) and the catheter] *to respective of the lumens in catheter 20. First tube 26 communicates through junction 32 with intake lumen 50 in inner tube 48. Thus, first tube 26 will on occasion hereinafter in the alternative be referred to as intake tube 26. Second tube 28 communicates through junction 32 with the part of return lumen 52 formed between inner tube 48 and outer tube 60 in proximal portion 34 of catheter 20. Second tube 28 will on occasion hereinafter in the alternative be referred to as outlet tube 28.*

Catheter 20 is completed by *the* provision of an attachment in the form of a wing structure **54** *that can be* used to hold [the] catheter *20* in place in a patient in conventional fashion. It is preferable that [the] wing structure *54* be rotatable on [the] catheter *20,* and provision is made for [this with] *the* longitudinal [location provided by] *positioning of wing structure 54 along catheter 20 between* a tapered sleeve **56** and [a] *the* distal end of [the] *proximal* portion **34**. These parts are elements of [the] transition portion **36** *of catheter 20* as will be explained with reference to FIG. **3**.

[The] *Withdrawal* side opening[s] **40** and *return side openings* **42** are typical of openings that can be provided around the periphery of [the] catheter *20* to ensure flow into and out of [the] catheter *20* from anywhere about [the] catheter *20*. Consequently, if [the] catheter *20* should be positioned so that some of the *side* openings are occluded by engagement with the wall of a vein, other *of the side* openings will provide the essential flow.

Reference is next made to FIG. **3** to describe a preliminary step in the manufacture of the catheter. As seen in FIG. **3**, outer tube **46** extends through the tapered sleeve **56**, then through a tubular central part **58** of the wing structure **54**, and ends inside a distal end of the outer tube **60** of the proximal portion **34**. Details of this arrangement will become evident as the method of assembly is described.

As a preliminary, the outer tube **46** is placed in a suitable conventional injection moulding machine and positioned suitably to mold the sleeve **56** about the tube. The materials are compatible thermoplastics so that the sleeve becomes an integral part of the tube **46**. Next, the outer tube is used in an assembly shown in FIG. **4**. In this step the inner tube **48** has a leading part indicated by numeral **68** within a corresponding part **70** of the tip section **38**. These parts can of course be deformed to fit together in this way, but as shown, round tubing is selected for these parts so that they fit within one another quite readily but at the same time quite closely. If preferred, the parts can be attached to one another using a suitable adhesive. Typically the inner tube is #6 French and the tip section #8 French. After this step has been completed, the outer tube **46** is placed about the inner tube **48** and a leading part **72** of the outer tube overlaps part **70** of the tip section. Consequently the parts **68**, **70** and **72** are located about one another. Again an adhesive can be used to fix the assembly.

A tubular cylindrical mandrel **74** is proportioned to fit inside the outer tube **46** and about the inner tube **48**. Typically the outer tube is #12 French and the materials of all of the inner and outer tubes and the tip section are polyurethane with the selection of the materials being chosen to give the physical characteristics desired. For instance if a soft tip is required, then a material of a suitable Durometer is provided for the tip section **38** and of course sufficient rigidity must be provided in the outer tube **48** to ensure that the catheter is stable during insertion and when in place. It should be noted that the inner tube is protected to some extent against collapse by the outer tube so that the inner tube can be of a relatively soft thin walled polyurethane. As will be described, this assists in forming the U-shaped proximal portion **34** as well as maximizing the space available for flow in the catheter.

A solid second mandrel **76** is provided to support the inner tube so that this tube extends between the mandrels **74** and **76**. Mandrel **74** has a rounded end and stops against the part **70** of the tip section **38** whereas the inner mandrel **66** projects into the tip section **38**. This provides support along the space occupied by two halves of a mold **78** which are operable to move into contact with the assembly.

The mold **78** is used to form the transition portion **39** by moving the mold halves into contact with the assembly shown in FIG. **4** under the influence of heat and pressure sufficient to cause the material of the parts **68**, **70** and **72** to flow. Once this is completed the structure is allowed to cool and the mandrels removed. The result is shown in FIG. **5**.

As seen in FIG. **5**, [the] intake lumen **50** terminates at a blind annular end wall **80** at [the] *distal* transition portion **39**. [The intake] *Intake* lumen **50** is contained between outer tube **46** and inner tube **48** [and the] *in main section 37. Withdrawal* openings **40** are provided immediately adjacent [the] *distal* transition portion **39** to allow blood flow into [the] *intake* lumen **50**. More *withdrawal* openings can [of course] be provided further away from [the] *distal* transition portion [(] *39,* as seen in FIG. **1**[) if required].

The return lumen **52** formerly described with reference to the inner tube **48**, [now] continues *distally* through [the] *distal* transition portion[,] **39** and through [the] tip section **38**. [The] *Distal* transition portion *39* ends [the] intake lumen **50** and blends smoothly from the outer surface of [the] tip section *38* to the outer surface of [the] main section *37*, and in particular to the outer surface of [the] outer tube **46**.

It should be noted in FIG. **5** that the three parts[, namely the] *68, 70, 72, variously of* outer [and] *tube 46,* inner tube[s **46**,] **48**, and [the] tip section **38**[,] are shown as three individual parts by the [shading] *use of contrasting cross hatching*. Where [they] *parts 68, 70, 72,* meet at [the] *distal* transition portion **39**, [the shading] *cross hatching* has been omitted, because [this is a] *at distal transition* portion [where] *39* the materials *of parts 68, 70, 72,* flow into one another, [and it is] *rendering* indefinite where *each of* the parts *68, 70, 72,* begin*s* and end*s* after molding. [However by] *From a* comparison between FIGS. **4** and **5** it is evident that [the] parts **68**, **70** blend into one as do [the] parts **70** and **72**, resulting in [the] *distal* transition portion [**36**] *39*. Preferably, [the] parts *68, 70, 72,* are all polyurethane [with the] *of* grades and sizes [being] chosen to provide [the] desired physical characteristics, such as a soft pliable tip section *38* and a stiffer outer tube *46* with a thin walled inner tube *48*.

After the assembly has been molded as demonstrated in FIGS. **4** and **5**, the tip section **38** is deformed in a conventional manner to create a tapered tip **82** about the end opening **44**.

Next the proximal transition portion **36** is completed. Referring to FIG. **3**, the standard wing structure **54** is slipped over the outer tube **46** into engagement with the tapered sleeve **56**. Next the proximal outer tube **60** of the U-shaped proximal portion **34** is slipped over the inner tube **48** (not shown in FIG. **3**) and engaged on the tube **46**. The tube **60** is held in place by chemical bonding or heat sealing in a position which permits the wing structure to rotate. This assembly takes place before the tube **60** is bent. It should be noted that the numeral **54** could also indicate a conventional cuff which would be located in the same way as the wing structure.

The assembly is now complete from the proximal transition portion **36** to the distal end of the catheter. The outer tube **60** of the portion **34** contains part of the inner tube **48** which, as was described, ends at and is anchored in, the distal transition portion **39**. The next step is to give the proximal portion **34** its U-shape. To do this, a flexible tubular mandrel indicated as **86** in FIG. **6** is engaged over the inner tube **48** and inside the outer tube **60**. The mandrel is of a synthetic elastomeric material, preferably that sold under the trademark TEFLON.

As seen in FIG. **6**, the mandrel **86** is pushed until it reaches the proximal transition portion **36** and then the portion **34** is curved manually to fit into a die indicated diagrammatically by numeral **87**. This die has a channel to receive the portion **34** and a similar second part of the die closes over the first part to trap the portion **34** in the desired U-shaped configuration. The die and catheter are then subjected to heating to about 120 degrees C. (250 degrees F.) to cause the inner and outer tubes to take a new set. The mandrel resists this temperature.

After cooling in the die, the proximal portion **34** has a U-shaped configuration as seen in FIGS. **1** and **6**.

The last step is to form the proximal end structure or junction **32** reference is now made of FIG. **7**. After trimming the inner and outer tubes **48**, **60** as required, the assembly is prepared by first positioning a proximal end of the proximal portion **34** in a mold (not shown) which is to create the junction **32** by injection molding using conventional techniques. The portion **34** is positioned using first and second mandrels **94**, **96**. The mandrel **96** has a cylindrical portion **98** blending into a converging generally conical portion **100**, which in turn blends into a cylindrical end part **102** angled with respect to the portion **100**. The part **102** fits closely inside a proximal end of the inner tube **48** and this tube is maintained in a position in engagement with the outer tube **60** by the mandrels **94**, **96**.

The mandrel **94** has an outer cylindrical portion **104** which blends into a converging and generally conical portion **106** ending at a projection **108**. This projection has a generally U-shaped cross-section (as will be explained) and is angled with respect to the conical portion **106**.

The projection **108** on the end of the mandrel **94** is shaped to fit the space provided *between outer tube 60 and inner tube 48,* when **[**the**]** inner tube **48** is held *by mandrel 96* against the inner surface of **[**the**]** outer tube **60**. As a result **[**it**]** *projection 108* has a generally U-shaped configuration. The angular offset**[**s**]** of **[**the**]** projection **108** *of mandrel 94* and **[**the**]** *the angular offset of* end part **102** of **[**lumen**]** *mandrel* **96** result in **[**the**]** projection *108* and end part **102** extending in parallel axially with respect to *axis L of* the *end of* proximal portion **34** *at junction 32*. **[**The cylindrical**]** *Cylindrical* portion**[**s**]** **98** *of mandrel 96* and *cylindrical portion* **104** *of mandrel 94 can thus be assembled as shown in FIG. 7 so as to* diverge sufficiently with respect to the **[**axial main section**]** that the ends of **[**the respective**]** intake *tube 26* and outlet tube**[**s **26**,**]** **28** can be accommodated on **[**the**]** mandrels *94, 96, respectively,* with the ends *of intake tube 26 and of outlet tube 28* positioned in the mold to become entrapped in the junction **32**.

Once the assembly shown in FIG. **7** has been completed, the mold is closed and injection takes place to form the junction **32**. The material is preferably polyurethane although other materials can be used provided that the usual requirements of compatibility etc. are met.

The mandrels are removed, and because there is some flexibility in the material, the mandrels can be pulled out without causing any damage.

The structure shown in FIG. **7** has particular significance in the resulting flow through the catheter. Unlike previous co-axial catheters, the flow tends to remain linear due to the fact that the intake and return tubes **26**, **28** are generally in line with the portion **34**. Previously, one of these tubes was in line and the other was connected through the side of the junction so that the flow must pass through a significant angle which in some instances approached 90 degrees. This is most undesirable because any changes in direction of this kind will result in turbulance in the blood flow with potential for damage to the blood. It is well established that pressure fluctuations in blood flow paths should be minimized, and this structure tends to limit such variations.

The angle shown as "A" in FIG. **7** indicates the divergence between **[**the**]** *intake and outlet* tubes **26**, **28** **[**as they meet the**]** *at* junction **32**. Because of the construction it is possible to maintain this *divergence* angle *A* in the order of 15 to 20 degrees, **[**and is**]** readily **[**maintained**]** below 30 degrees. As a result, the flow *of fluid* into and out of **[**the**]** catheter *20* is essentially axial with reference to the *end of proximal* portion **34** at *junction 32 at* all times. This is because the angle of each of **[**the**]** *first and second access* tubes **26**, **28** with reference to **[**the**]** axis *L* of **[**the**]** *proximal* portion **34** **[**where it meets the**]** *at* junction **32** is half of the range up to 30 degrees.

[The catheter is now complete but for the final shaping of the proximal portion **34**. Up to this point this portion has remained straight and consists of the outer tube **60** and part of the inner tube **48** which starts at the junction **32** (FIG. **1**) and ends at the distal transition portion **39**.

Reference is now made to FIG. **7** to describe forming the proximal portions **34**.**]**

The catheter shown as a preferred embodiment is typical of catheters that could be made in accordance with the invention. As mentioned earlier it is possible to proportion the tip and/or provide soft material for the tip to ensure that after insertion the tip will flex and will not damage veins. At the same time, there is sufficient rigidity in the transition portion to maintain the relationship between the tip and the inner and outer tubes so that the intake lumen **50** remains patent while the insertion takes place and during use.

It will be apparent that the structure can be varied within the scope of the invention. In particular, the tip section need not be tapered and in some cases (depending upon requirements) the distal end of the catheter could be closed. Also, the proximal transition portion could be arranged with a cuff instead of the wing structure **20**. Either of these attachments can be used advantageously.

The proportions of the parts can be varied and it would be possible to do some preforming before assembly.

In a typical embodiment *of catheter 20* the various tubes used in the structure are polyurethane. **[**The outer**]** *Outer* tube **46** is a firm polyurethane having a 65D Durometer**[**. It is**]** , *a* 3.175 mm inside diameter, and *a* 3.734 mm outside diameter. **[**The tip**]** *Tip* section *38* is also 65D *Durometer, but*

with an inside diameter of 1.727 mm and an outside diameter of 2.667 mm. [The inner] *Inner* tube *48* is of a soft, thin-walled polyurethane dimensioned to [fit into] *extend through* the assembly shown in FIG. **3**[, and the] *with sufficient clearance between the exterior of inner tube 48 and the interior of that assembly to result in the creation of intake lumen 50 therebetween. Inner tube 48 has a wall thickness that is less than the wall thickness of outer tube 46. Outer* tube **60** is proportioned to fit [over the] *about* outer tube **46** *in the manner illustrated in FIG. 3, whereby the cross section of outer tube 60 and the associated area of the cross section of outer tube 60 are greater, respectively, than the cross section of outer tube 46 and the associated area of the cross section of outer tube 46*. [The] *Outer* tube **60** has a wall thickness of about 1.31 mm and a hardness of 85A *Durometer* to minimize the risks of kinking and to protect [the] inner tube *48*.

It is important to note that [this] catheter *20* overcomes disadvantages in the art.

Firstly, the structure *of catheter 20* is such that [the] inner tube *48* can be thin walled because it is protected by [the] stiffer outer tube **46** in [the] main section **37** and by [the] outer tube **60** in [the] curved proximal portion **34**. [The] *Thus,* thin-walled, soft inner tube *48* takes up minimal cross-sectional space, [thereby] permitting the portion of [the] co-axial catheter *20* which is to be inserted *into the body of a patent* to have a small[er] cross-section.

Another feature *of catheter 20* is the [fact that there is a] minimum of upwardly extending structure beyond [the attachment] *proximal transition portion* **36**, when [the] catheter *20* is placed in a jugular vein. This is very important to the comfort of the patient. Also, because attachment takes place where [the] catheter *20* exits the incision, manipulation of [the] *intake tube 26 and outlet* tube[s] *28* to make connections [etc.] will have less likelihood of dislodging or moving [the] catheter *20*.

The invention incorporates all variations within the scope of the claims and is not restricted to the embodiments disclosed.

I claim:

1. A co-axial dual lumen catheter comprising:

a main section having proximal and distal ends and including a first outer tube;

a tip section at said distal end;

an attachment at said proximal end for anchoring the catheter to a patient immediately adjacent an incision where the catheter entry is effected;

a U-shaped proximal portion having a distal end attached to the main section at said proximal end of the main section and having a proximal end, the proximal portion including a second outer tube;

a junction attached to the proximal end of the proximal portion;

an inner tube extending loosely inside the first and second outer tubes and anchored at the tip and the junction to define a return lumen and combining with the first and second outer tubes to define an annular intake lumen;

intake and outlet tubes attached to the junction, the tubes extending generally in parallel with the main section and to one side of the main section and being coupled to the respective intake and return lumens; and

the inner tube being thin walled relative to the wall thickness of the first outer tube, and the second outer tube having a greater cross-sectional area than the first outer tube.

2. A catheter as claimed in claim **1** in which the attachment is a wing structure.

3. A catheter as claimed in claim **1** in which the attachment is a cuff.

4. A catheter as claimed in claim **1** in which the first outer tube defines intake openings providing access into the intake lumen, and the tip section is of smaller cross-section than the main section, the tip section having at least one return opening.

5. A catheter as claimed in claim **4** and further comprising a transition portion at the distal end of the main section, the transition portion being formed of material provided in overlapping parts of the inner tube the tip section and the first outer tube, the inner tube being inside the tip section which is inside the first outer tube, the inner tube blending smoothly internally into the tip section at the transition portion and the outer tube blending smoothly externally into the tip section with the intake lumen ending at the transition portion, the tip section forming a continuation of the return lumen and the return lumen ending at said return opening.

6. A catheter as claimed in claim **5** in which the inner tube and the first outer tube are spaced from one another radially where the intake lumen terminates.

7. A catheter as claimed in claim **5** in which the transition portion is tapered smoothly to converge from the first outer tube to the tip section.

8. A catheter as claimed in claim **4** in which the inner tube, first and second outer tubes and tip section are round in cross-section.

9. A catheter as claimed in claim **8** in which the diameter of the tip section is greater than that of the inner tube and less than that of the first outer tube.

10. A co-axial dual lumen catheter comprising:

a main section having proximal and distal ends and including a first outer tube, the first outer tube extending along a longitudinal axis and defining intake openings;

a U-shaped proximal section *including a proximal and a distal end, said distal end of said U-shaped proximal section being* attached to the proximal end of the main section, the proximal section including a second outer tube[s];

an inner tube extending through the first and second outer tubes; the inner tube defining a return lumen and combining with the first and second outer tubes to define an annular intake lumen;

intake and outlet tubes;

a junction coupling the intake and outlet tubes to the proximal section with the intake tube coupled for receiving blood from the intake lumen and the outlet tube coupled for delivering treated blood to the return lumen; and

the intake and outlet tubes leaving the junction generally parallel with the main section and to one side of the main section and with an angle of divergence between the intake and the outlet tubes of less than about 30 degrees and spaced substantially equally to either side of an extension of [said] *the longitudinal* axis *of said U-shaped proximal section at said proximal end thereof.*

11. A catheter as claimed in claim **10** in which the angle of divergence is about 15 to 20 degrees.

12. A catheter as claimed in claim **10** in which the inner tube is located against the second outer tube inside the junction.

13. A co-axial dual lumen catheter for use in dialysis, the catheter comprising:

a main section for insertion and having a selected cross-section;

a tip section of smaller cross-section than the selected cross-section and attached to a distal end of the main section;

a U-shaped proximal section extending from a proximal end of the main section and having a cross-section greater than said selected cross-section;

the main section having a first outer tube of a selected wall thickness and having said selected cross-section and the proximal section having a second outer tube having a wall thickness greater than said selected wall thickness;

an inner tube extending from the tip section through the first and second outer tubes and having a wall thickness less than said selected wall thickness whereby an intake lumen is defined in the space between the inner tube and the first and second outer tubes, and a return lumen is defined by the inner tube and the tip section; and

a junction coupled to the inner tube and the second outer tube to facilitate connecting the catheter to dialysis equipment.

14. A catheter as claimed in claim **13** and further comprising a distal *transition* portion where the inner tube, tip section, and first outer tube of the main section meet, **[**the**]** *said* transition portion presenting a smooth tapered outer surface to facilitate insertion.

15. A co-axial catheter as claimed in claim **13** in which said junction includes intake and outlet tubes, the tubes being connected respectively to the intake and return lumens and lying generally parallel to the main section and to one side of the main section.

16. A catheter as claimed in claim **13** in which the inner tube, first outer tube and tip section are round in cross-section.

17. A catheter as claimed in claim **13** in which the tip section includes an opening at the distal end of the catheter.

18. A catheter as claimed in claim **13** in which the inner tube and the first outer tube are spaced from one another concentrically where the intake lumen terminates.

19. A catheter as claimed in claim **18** in which an end part of the inner tube is engaged inside a part of the tip section which in turn is engaged inside a part of the first outer tube to form a transition portion, and in which the transition portion is tapered smoothly to converge from the first outer tube to the tip section.

20. A dual lumen catheter as claimed in claim **19** in which the tip section is more flexible than the main section.

21. A dual lumen catheter comprising:

a main section having a proximal end and a distal end and comprising a first outer tube;

a tip section at said distal end of said main section;

a generally U-shaped proximal portion having a distal end and a proximal end, said distal end of said proximal portion being attached to said proximal end of the main section, and said proximal portion comprising a second outer tube;

a junction attached to said proximal end of said proximal portion;

an inner tube extending inside said first outer tube and said second outer tube and enclosing a return lumen, a first end of said inner tube being anchored at said tip section and a second end of said inner tube being anchored at said junction, said inner tube combining with said first outer tube and said second outer tube to define an annular intake lumen between said inner tube and said first and second outer tubes, each of said return lumen and said intake lumen communicating at the respective distal ends thereof with the exterior of said catheter.

22. A dual lumen catheter as recited in claim 21, further comprising an attachment structure secured between said proximal end of said main section and said distal end of said proximal portion, said attachment structure being capable of use for anchoring the catheter to the body of a patient immediately adjacent an incision through which said tip section and said main section of said catheter are entered into the body of the patient.

23. A dual lumen catheter as recited in claim 21, wherein the longitudinal axis of said proximal portion at said distal end thereof is parallel to the longitudinal axis of said proximal portion at said proximal end thereof.

24. A dual lumen catheter as recited in claim 21, wherein the cross section of said return lumen is circular.

25. A dual lumen catheter as recited in claim 21, further comprising:

an inlet tube attached to said junction and coupled therethrough with said intake lumen at said proximal end of said proximal portion; and

an outlet tube attached to said junction and coupled therethrough with said return lumen at said proximal end of said proximal portion.

26. A dual lumen catheter as recited in claim 25, wherein said outlet tube and said inlet tube at said junction form an angle of divergence of less than about 30°.

27. A dual lumen catheter as recited in claim 25, wherein said outlet tube and said inlet tube at said junction are disposed symmetrically on opposite sides of the longitudinal axis of said proximal portion at said proximal end thereof.

28. A dual lumen catheter as recited in claim 21, wherein the thickness of the wall of said inner tube is less than the thickness of the wall of said first outer tube.

29. A dual lumen catheter as recited in claim 21, wherein said second outer tube has an outer cross section that is greater than the outer cross section of said first outer tube.

30. A dual lumen catheter as recited in claim 21, wherein the outer surface of said tip section tapers radially inwardly to an end opening through which said return lumen communicates with the exterior of said catheter.

31. A dual lumen catheter as recited in claim 30, wherein a return opening is formed through the wall of said tip section proximal of said end opening thereof, said return lumen communicating through said return opening with the exterior of said catheter.

32. A dual lumen catheter as recited in claim 21, wherein an intake opening is formed through the wall of said first outer tube proximate said distal end of said main section, said intake lumen communicating through said intake opening with the exterior of said catheter.

33. A dual lumen catheter as recited in claim 32, wherein said intake lumen terminates distal of said intake opening.

34. A dual lumen catheter as recited in claim 21, wherein the outer cross section of said tip section is smaller than the outer cross section of said first outer tube.

35. A dual lumen catheter as recited in claim 34, further comprising a transition section located between said distal end of said main section and said tip section, the exterior of said transition portion tapering smoothly radially inwardly from said outer cross section of said first outer tube to said outer cross section of said tip section.

36. A dual lumen catheter as recited in claim 21, wherein said main section is substantially straight.

37. A dual coaxial lumen hemodialysis catheter, the catheter comprising:

a main section for insertion into the body of a patient, said main section having a proximal end and a distal end, said main section comprising a first outer tube;

a tip section attached to said distal end of said main section, said tip section having a smaller outer cross section than the outer cross section of said first outer tube;

a generally U-shaped proximal portion extending from said proximal end of said main section, said proximal portion comprising a second outer tube; and

an inner tube extending from said tip section through said first outer tube and said second outer tube and enclosing a return lumen that communicates with the exterior of said catheter through said tip section, the space between said inner tube and said first outer tube and said second outer tube defining an intake lumen; and

wherein the outer cross section of said proximal portion is greater than the outer cross section of said first outer tube.

38. A dual lumen catheter comprising:

a main section having a proximal end and a distal end;

a generally U-shaped proximal portion attached to said proximal end of said main section;

an inner tube extending through said main section and said proximal portion said inner tube defining a return lumen therewithin, and said inner tube combining with said main section and said proximal portion to define an intake lumen between said inner tube and said main section and said proximal portion;

a tip section at said distal end of said main section attached to a first end of said inner tube, the outer surface of said tip section tapering radially inwardly in a distal direction to an end opening through which said return lumen communicates with the exterior of said catheter; and

wherein the outer cross section of said proximal portion differs from the outer cross section of the main section.

39. A dual lumen catheter as recited in claim 38, wherein said outer cross section of said proximal portion is greater than said outer cross section of said main section.

40. A dual lumen catheter as recited in claim 39, further comprising a proximal transition portion intermediate said proximal portion and said main section, said proximal transition portion tapering radially inwardly in a distal direction smoothly interconnecting the outer surface of said proximal portion with the outer surface of said main section.

41. A catheter comprising:

a main section having a proximal end and a distal end;

a generally U-shaped proximal portion attached to said proximal end of said main section;

a central conduit extending through said proximal portion and said main section and projecting distally beyond said distal end of said main section,

the portion of said central conduit projecting distally beyond said distal end of said main section defining a tip section projecting from said distal end of said main section and having a smaller outer cross section than the outer cross section of said main section at said distal end thereof,

said central conduit defining therewithin a return lumen, and

said central conduit in combination with said proximal portion and said main section defining an intake lumen between the exterior of said central conduit and the interiors of said proximal portion and said main section;

a distal transition portion at said distal end of said main section terminating the distal extent of said intake lumen and smoothly and continuously interconnecting the outer surface of said main section with the outer surface of said tip section;

attachment means on the distal end of said proximal portion for anchoring said catheter to the skin of a patient, when said main section and said tip section are implanted in the body of the patient;

a junction at the end of said proximal portion opposite from said main section; said junction being attached to the proximal end of said central conduit;

an inlet tube attached to said junction and coupled therethrough to said intake lumen; and

an outlet tube attached to said junction and coupled therethrough to said return lumen, said inlet tube and said outlet tube being positioned on a single side of said main section.

42. A cardiovascular access catheter comprising:

an outer conduit having a distal end and a proximal end, a portion of said outer conduit adjacent said proximal end thereof being configured into a generally U-shaped proximal portion;

a central conduit extending through said outer conduit from said proximal end to said distal end thereof and projecting distally beyond said distal end of said outer conduit,

the portion of said central conduit projecting distally beyond said distal end of said outer conduit defining a tip section projecting from said distal end of said outer conduit and having a smaller outer cross section than the outer cross section of said outer conduit at said distal end thereof,

said central conduit defining therewithin a return lumen, and

said central conduit and said outer conduit defining an intake lumen between the exterior of said central conduit and the interior of said outer conduit;

a distal transition portion at said distal end of said outer conduit terminating the distal extent of said intake lumen and smoothly and continuously interconnecting the outer surface of said outer conduit at said distal end thereof with the outer surface of said tip section; and

means for affording fluid access individually to the proximal end of said return lumen and to the proximal end of said intake lumen.

43. A cardiovascular access catheter as recited in claim 42, wherein said means for affording access comprises:

a junction interconnecting said proximal end of said outer conduit with said proximal end of said central conduit;

an inlet tube attached to said junction and coupled therethrough to said intake lumen; and

an outlet tube attached to said junction and coupled therethrough to said return lumen, said inlet tube and said outlet tube being generally parallel with the portion of said outer conduit distal of said U-shaped proximal portion, being disposed on a common side thereof, and being spaced substantially symmetrically to either side of the longitudinal axis of said proximal section at said proximal end thereof.

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